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VIA ELECTRONIC FILING

Honorable Stanley R. Chesler, U.S.D.J.
U.S. District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: *Sanofi-Aventis U.S. LLC, et al. v. Mylan GmbH, et al.*
Civil Action No. 2:17-cv-09105-SRC-CLW

Dear Judge Chesler:

We, along with Wilson Sonsini Goodrich & Rosati, represent Defendants in the above matter. Because Sanofi has asserted it would be entitled to an injunction under 35 U.S.C. §271(e)(4)(A) (ECF No. 561 at 4-5), in the unlikely event that Sanofi's request for relief needs to be considered, we respectfully submit that it is imperative for the Court to be informed of substantial obstacles with respect to Sanofi's assertions. For these reasons, Defendants' February 12, 2020 letter (ECF No. 567) respectfully requested an opportunity to fully brief for the Court any injunction-related issues, if it were to become necessary, and Defendants reiterate their request here.

A prime example of why this is important is provided by the recent First Circuit Court of Appeals decision in an antitrust suit filed against Sanofi concerning Lantus SoloSTAR. Specifically, the First Circuit held that Sanofi's listing of a device patent in the Orange Book for Lantus SoloSTAR—which patent was originally asserted in this case—was improper, potentially subjecting Sanofi to antitrust liability. *In re: Lantus Direct Purchaser Antitrust Litigation*, No. 18-2086, 2020 U.S. App. LEXIS 4565 (1st Cir. Feb. 13, 2020) ("*Lantus Antitrust*"). A copy of the decision is attached as Exhibit A for the Court's convenience.

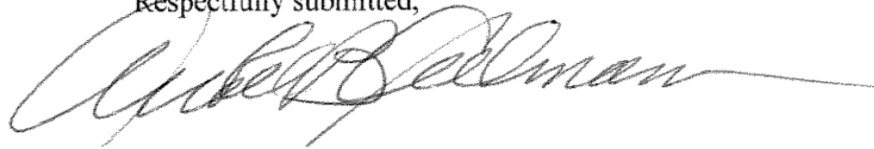
Briefly, plaintiffs in *Lantus Antitrust* allege Sanofi restricted competition in the insulin glargine market by improperly listing patents in the Orange Book to "extend[] its monopoly" by "delaying competition" and allowing Sanofi to maintain "inflated prices." Ex. A at *9. The First Circuit reversed the district court's grant of Sanofi's motion to dismiss after conducting a detailed analysis of U.S. Patent No. 8,556,864 ("864 patent")—which is analogous to the '844 patent at issue here—and the FDA's Orange Book listing regulations. The First Circuit concluded that because the '864 patent does not "claim the drug," let alone even "mention

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insulin glargine or the Lantus SoloSTAR at any point,” Sanofi’s listing of the patent in the Orange Book was improper. *Id.* at *8, *13-14, *17-18, *19. Because the same analysis is applicable to the ’844 patent, Sanofi’s contention that the ’844 patent “is properly listed in the Orange Book” (ECF No. 561 at 5) is certainly subject to challenge, and the First Circuit’s decision provides yet another reason (in addition to non-infringement and invalidity) why Sanofi is not entitled to any injunctive relief under §271(e)(4)(A).

We thank the Court for its consideration and assistance in this matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Arnold B. Calmann", with a long horizontal flourish extending to the right.

Arnold B. Calmann

cc: All Counsel of Record (by CM/ECF)